OCT 2 2 2001

510(k) Summary
Dutch Ophthalmic, USA
D.O.R.C. CryoStar Cryosurgical System
(per 21 CFR 807.92)

K012821

1. SUBMITTER NAME AND ADDRESS

Dutch Ophthalmic, USA
One Little River Road
P.O. Box 968
Kingston, NH 03848

Contact Person: Mark W. Furlong, President
Telephone: 603-642-8468

Date Prepared: August 22, 2001

2. DEVICE NAME

Proprietary Name:	D.O.R.C. CryoStar Cryosurgical System
Common/Usual Name:	Cryosurgical System
Classification Name:	Unit, Cryophthalmic, AC-Powered (HRN & 21CFR 886.4170)

3. PREDICATE DEVICES

Manufacturer	Product Name	510(k) Number
Spembly Medical Ltd	D.O.R.C. Cryo 1500	K940373
Spembly Medical Ltd	Keeler Cryo Master	K992954

4. DEVICE DESCRIPTION

The D.O.R.C. CryoStar Cryosurgical System consists of a cryogen gas bottle, a console, an ophthalmic probe, a footswitch and necessary interconnections. The console controls delivery of the gas to the probe. It also processes signals from the footswitch, enabling the probe to freeze and defrost.

5. INTENDED USE

The D.O.R.C. Harmony CryoStar Cryosurgical System is a surgical system for ophthalmic surgery intended for use in surgery of the posterior segment or anterior segment including cryopexy for retinal detachment, glaucoma, cataract extraction, trichiasis, and retinopathy of prematurity.

K012821

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

Operational and technological characteristics form the basis for the determination of substantial equivalence of the D.O.R.C. CryoStar Cryosurgical System with legally marketed predicate devices. Information supplied in this premarket notification includes descriptive information about the intended use, operation and technological characteristics. The following table summarizes the technological characteristics of the D.O.R.C. CryoStar Cryosurgical System in comparison to the predicate devices.

CRYOSTAR COMPARISON CHART

Significant Feature	DORC *CryoStar*	DORC Model 1500	Keeler Cryomaster
CONSOLE			
Basic technology	Electro-mechanical	Electro-mechanical	Electro-mechanical
Software content	Non-programmable firmware	None	Non-programmable firmware
Pressure control	Manual	Manual	Manual
Temperature measurement	Thermocouple (for some probes in range only)	Thermocouple (for some probes in range only)	Thermocouple (for some probes in range only)
Indicator panel:			
• timer	Digital display	None	Digital display
• pressure	LED array	Dial gauge	Digital display
• temperature	LED array	LED array	Digital display
Power source	Mains	Battery	Mains
Gas inlet	Screw connection	Screw connection	Screw connection
Gas outlet	Barbed fitting	Barbed fitting	Barbed fitting
Probe connection	Screw fitting	Screw fitting	Bayonet fitting
PROBES	Ophthalmic standard freeze and end-freeze, some with thermocouples. Re-usable when sterilised by autoclaving	Ophthalmic standard freeze and end-freeze, some with thermocouples. Re-usable when sterilised by autoclaving	Ophthalmic standard freeze and end-freeze, some with thermocouples. Re-usable when sterilised by autoclaving
ACCESSORIES			
Probe adaptor	Universal (suits probes with or without thermocouples)	None	One adaptor for probes with thermocouples and one adaptor for those without
CONSUMABLE CRYOGEN GASES			
Nitrous oxide	Medical grade, vapour withdrawal gas	Medical grade, vapour withdrawal gas	Medical grade, vapour withdrawal gas
Carbon dioxide	Medical grade, vapour withdrawal gas	Medical grade, vapour withdrawal gas	Medical grade, vapour withdrawal gas

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 2001

Mr. Mark Furlong
President
Dutch Ophthalmic USA, Inc.
One Little River Rd.
P.O. Box 968
Kingston, NH 03848

Re: K012821
Trade/Device Name: D.O.R.C. CryoStar Cryosurgical System
Regulation Number: 21 CFR 886.4170
Regulation Name: Cryophthalmic Unit
Regulatory Class: Class II
Product Code: HRN
Dated: August 22, 2001
Received: August 23, 2001

Dear Mr. Furlong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K012821

Device Name: D.O.R.C. CryoStar Cryosurgical System

Indications For Use:

The D.O.R.C. CryoStar Cryosurgical System is a surgical system for ophthalmic surgery intended for use in surgery of the posterior segment or anterior segment including cryopexy for retinal detachment, glaucoma, cataract extraction, trichiasis and retinopathy of prematurity.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

10-15-01

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012821

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)